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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,630	CLARKE, ALLAN J.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7,8,11-14,20,21,23-27,29-32,37-41 and 51-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7,8,11-14,20,21,23-27,29-32,37-41 and 51-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 05/12/09 and the Request for Continued Examination filed on 06/05/09 are acknowledged.

2. Claims 2-3, 5-6, 9-10, 15-19, 22, 28, 33-36, and 42-50 were cancelled.

3. Claims 1, 11-12, 21, 52-55 and 57-59 were amended.

4. Claims 1, 4, 7, 8, 11-14, 20,21, 23-27, 29-32, 37-41 and 51-59 are included in the prosecution.

Continued Examination under 37 CFR 1.114

5. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/05/09 has been entered.

Response to Arguments

Objection to the Specification

6. In light of Applicant's amendment to the Specification, the objection of 03/12/09 is withdrawn.

Claim objections

7. In light of Applicant's amendment of claims 11, 21, 52-54 and 57-58, the objections of 03/12/09 are withdrawn.

Rejection of claims under 35 USC § 112, second paragraph

8. In light of Applicant's amendments of claims 1, 12 and 59, the rejections under 35 USC § 112, second paragraph are withdrawn.

Rejection of claims under 35 USC § 103(a)

9. Applicant's arguments, see Page 11, filed 05/12/09, with respect to the rejection of claims 1, 4, 7, 11-14, 20-21, 23-25, 27, 29-32, 37-41 and 51-59 under 35 USC § 103(a) as being unpatentable over Breitenbach et al. (US 6,150,424) in view of Jane et al. (US 5,710,190) have been fully considered but are not found persuasive.

Applicant argues that claim 1 of Breitenbach requires a thermoplastic polymer and that Applicants do not require a thermoplastic polymer.

This is not persuasive because instant claims recite the transitional phrase "comprising" which is open language and does not exclude any other polymers. Breitenbach also teaches foamed active ingredient preparations comprising bulking agents (mannitol, sorbitol, xylitol) which are the non-thermosetting polymerized plastics material of instant claim 1. Breitenbach teaches starch which is the non-thermosetting modifier.

Applicant argues that the explanation regarding "comprising" transitional language is clearly missing the point that the Breitenbach et al. invention requires the use of a thermoplastic polymer.

This is not persuasive because, instant claim 1, as presently amended does not exclude a thermoplastic polymer.

Applicant amended claim 1 to include the following limitation: "the molded microcellular polymeric material and pharmaceutically active agent are injection molded

into the pharmaceutical dosage form". Applicant argues that this further distinguishes Applicant's claimed invention over the Breitenbach et al. patent.

This is not persuasive because a combination of references (Breitenbach and Jane) was applied against instant claim 1. The secondary reference, Jane, teaches injection molding (Col. 6, lines 24-30). The limitations of the composition are rendered obvious by the polyols (mannitol, sorbitol and xylitol), starches (Col. 2, lines 58-60, Col. 3, lines 21-22 and Col. 3, lines 33-35), the active ingredients (Col.1, line 38 to Col. 2, line 38), and lubricants (Col. 3, lines 52-55) taught by Breitenbach in view of the cellulose derivatives such as methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose (Col. 4, lines 58-62) and injection molding (Col. 6, lines 24-30) taught by Jane. Since all the claimed elements are found in Breitenbach and Jane, one with ordinary skill in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Applicant argues that the Examiner has not established any reason that the present invention would be obvious over the cited art of Breitenbach whether or not in view of any secondary references. Applicant argues that there is no "proposed modification of the applied reference" under any circumstance that could be used to arrive at Applicants claimed subject matter.

This is not persuasive because it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a solid, foamed active

ingredient preparation, as taught by Breitenbach, combine it with the foamed microcellular composition, as taught by Jane, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Jane teaches that the foamed microcellular composition has the advantages of excellent biodegradability, water resistance, and a low cost production" (Col. 2, lines 11-24). Moreover, combining prior art elements according to known methods to yield predictable results would have been obvious. Please see MPEP 2141. Both Breitenbach and Jane are concerned with solid, foamed compositions and are properly combinable.

Applicant argues that claim 21 requires a rigid microcellular foam which is not taught nor suggested by Breitenbach.

This is not persuasive because Breitenbach teaches **solid**, foamed active ingredient preparations (Col. 1, lines 5-7). One of ordinary skill in the art would know that solid means rigid and would properly apply the Breitenbach reference for preparing a solid or rigid foamed preparation.

Applicant argues that the formulation and the process of using this formulation to make injection molded tablets will be, and is, fundamentally. Applicant questions the reasons for making the necessary modifications to the formulation if the use of that formulation is different.

This is not persuasive because the deficiency in Breitenbach is of a non-thermosetting polymer. This deficiency is taught by Jane and the combination of the two references renders the limitations of instant claim 1 obvious.

Applicant argues that claim 23 recites a further limitation in which the voids of the microcellular foam are in the form of closed cells and that Breitenbach does not teach nor suggest this result from their pharmaceutical dosage form or by combining the teachings of Breitenbach with the secondary references.

This is not persuasive because the limitation of the closed cell foam (claim **20**) is rendered obvious by the closed cell structure taught by Jane (Col. 8, lines 12-14).

Applicant argues that claim 40 requires that the rigid microcellular foam is enclosed within a skin having a density substantially greater than that of the microcellular foam, but having the same composition as that of the solid mixture.

This is not persuasive because the limitation of the rigid microcellular foam that is enclosed within a skin would have been obvious over the “closed active ingredient forms, i.e., forms in which the layer comprising active ingredient is completely enveloped by a layer without active ingredient” as taught by Breitenbach (Col. 5, lines 9-60). Breitenbach teaches the "production of multilayer partially or completely foamed forms comprising active ingredients by coextrusion. This entails at least two compositions ... at least one of which comprises an active ingredient and at least one of which is impregnated …” (Col. 5, lines 9-15). One with ordinary skill in the art would find it obvious to completely impregnate the active ingredient layer with another active ingredient layer during the process of routine experimentation.

Applicant argues that claim 41 requires the overall density of the dosage form to be substantially less than that of stomach fluids, whereby the dosage form is gastro-retentive and this limitation is not taught nor suggested by Breitenbach alone or in combination with the secondary references.

This is not persuasive because Breitenbach teaches that "the degree of foaming of the active ingredient preparation can be controlled by the amount of blowing agent added and the extrusion temperature. A high degree of foaming results in a lower density and thus a high rate of dissolution of the active ingredient form" (Col. 4, lines 61-65). One with ordinary skill in the art would modify the density of the dosage form with respect to the density of stomach fluids during the process of routine experimentation in order to make the dosage form gastro-retentive.

Applicant argues that the Breitenbach formulations are simple mixtures that cannot attain the degree of microcellular foam structure required by claim 21. Applicant has not provided any evidence that the combination of Breitenbach and Jane would not produce a solid, foamed microcellular composition.

Applicant argues that there is no disclosure in Breitenbach alone or taken with the Jane reference that teaches the specific combination of a polyol and the non-thermoplastic polymer or modifier as the matrix of the resulting tablet.

This is not persuasive because the limitations of the composition are rendered obvious by the polyols (mannitol, sorbitol and xylitol), starches (Col. 2, lines 58-60, Col. 3, lines 21-22 and Col. 3, lines 33-35), the active ingredients (Col.1, line 38 to Col. 2, line 38), and lubricants (Col. 3, lines 52-55) taught by Breitenbach in view of the cellulose derivatives such as methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose (Col. 4, lines 58-62) and injection molding (Col. 6, lines 24-30) taught by Jane. Since all the claimed elements are found in Breitenbach and Jane, one with ordinary skill in the art could have combined the elements and the combination would have yielded

predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Applicant argues that De Bock teaches a starch based formulation which can be extruded, not injection molded, as required by amended claim 1. Applicant argues that De Bock does not teach the inclusion of an active pharmaceutical agent in the resulting article.

This is not persuasive because De Bock is combined with Breitenbach and Jane. Breitenbach teaches the active ingredients (Col. 1, line 38 to Col. 2, line 38). Jane teaches injection molding (Col. 6, lines 24-30). De Bock teaches the maltodextrins (Col. 3, lines 50-52). Therefore, the combination of references renders instant claims 8 and 26 obvious.

Therefore the rejections of 03/12/09 are maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 4, 7, 11-14, 20-21, 23-25, 27, 29-32, 37-41, and 51-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US 6,150,424) in view of Jane et al. (US 5,710,190).

The claimed invention is a pharmaceutical dosage form suitable for oral administration comprising a molded microcellular polymeric material and a pharmaceutically acceptable active agent. The molded microcellular polymeric material

is a non-thermosetting polymerized plastics material comprised of at least one polyol selected from lactitol, xylitol, erythritol, sorbitol, maltitol, or mannitol, or combinations thereof; and at least one of a) non-thermosetting modifier selected from a starch, maltodextrin, a dextrose equivalent, polyalditol, a hydrogenated starch hydrosylate, or a mixture thereof; and/or b) a non-thermosetting polymer selected from carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof. The molded microcellular polymeric material and pharmaceutically active agent are injection molded into the pharmaceutical dosage form.

Breitenbach teaches solid, foamed active ingredient preparations based on melt-processable polymers (Col. 1, lines 5-7). Suitable active ingredients include analgesics (acetylsalicylic acid), antibiotics (amoxicillin), antidepressants (fluoxetine) and antihypertensives (verapamil) (Col. 1, line 38 to Col. 2, line 38). “The active ingredient preparations may furthermore also comprise starches …” (Col. 3, lines 21-22). Conventional pharmaceutical ancillary substances such as bulking agents (mannitol, sorbitol, xylitol), lubricants (stearates of aluminum or calcium), plasticizers (polyethylene glycol), dyes and stabilizers that can be included in the preparation are also disclosed (Col. 3, lines 26-60). “The degree of foaming of the active ingredient preparation can be controlled by the amount of blowing agent added and the extrusion temperature. A high degree of foaming results in a lower density and thus a high rate of dissolution of the active ingredient form” (Col. 4, lines 61-65). “The foamed active ingredient preparation

is subsequently shaped to the required active ingredient forms … by pelleting, granulating or tableting by known processes" (Col. 5, lines 2-5).

Breitenbach does not expressly teach a molded microcellular dosage form wherein the molded microcellular polymeric material and pharmaceutically active agent are injection molded into the pharmaceutical dosage form.

Jane teaches "… a biodegradable, soy protein-based thermoplastic composition. The composition is made of soy protein combined with a foaming agent, an organic plasticizing agent, and an aqueous medium such as water, and additives as desired. Articles formed from the composition have a foamed, cellular structure, and are biodegradable and possess a high degree of tensile strength, low density, and water resistance." (Col. 1, lines 42-51). "The composition is composed of about 100 parts soy protein that is preferably soy protein isolate, … and about 0.1-10 parts of a foaming agent, … about 5-60 parts of an organic plasticizing agent that is preferably glycerol, ethylene glycol or propylene glycol, and about 5-50 parts aqueous medium which is preferably water. One or more additives such as a filler, lubricant, colorant, preservative, and bleaching/whitening agent, can be included as desired" (Col. 1, lines 54-65). "The mixture can be molded into an article by compression molding" (Col. 2, lines 3-4). "Advantages of the protein based thermoplastics include excellent biodegradability, water resistance, and a low cost production" (Col. 2, lines 11-24). Polyethylene glycol is disclosed as a plasticizer, along with mannitol and maltitol (Col. 3, lines 51-64). Starches including corn or wheat starch can be used as fillers (Col. 4, lines 36-44). "Natural and modified gums such as xanthan gum, guar gum, locust bean gum, gum arabic, alginates, carrageenan, pectin, agar, konjac flour, and the like, can also be

included as a filler in the composition" (Col. 4, lines 54-57). Cellulose derivatives such as methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose can also be used as fillers (Col. 4, lines 58-62). Lubricants and colorants are disclosed (Col. 5, lines 11-35). Examples disclose molded articles with a foamed appearance and a closed cell structure with an average cell diameter of about 50μm (Col. 8, lines 12-14). Injection molding is disclosed (Col. 6, lines 24-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a solid, foamed active ingredient preparation containing starch, polyols (mannitol, sorbitol, xylitol) as taught by Breitenbach, combine it with the foamed microcellular composition and injection molding, as taught by Jane, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Jane teaches that the foamed microcellular composition has the advantages of excellent biodegradability, water resistance, and a low cost production" (Col. 2, lines 11-24). Since all the claimed elements are found in Breitenbach and Jane, one with ordinary skill in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a pharmaceutical dosage form would have been obvious over the solid, foamed active ingredient preparation that can subsequently be shaped by pelleting, granulating or tableting by known processes, as taught by Breitenbach (Col. 1, lines 5-7 and Col. 5, lines 2-5). The limitation of a molded microcellular polymeric material and a non-thermosetting polymerized plastics material would have been obvious over the starches, mannitol, sorbitol and xylitol as taught by Breitenbach (Col. 2, lines 58-60, Col. 3, lines 21-22 and Col. 3, lines 33-35). The limitation of the molded polymeric material would have been obvious over the molding of the mixture as taught by Jane (Col. 2, lines 3-4). The limitation of a pharmaceutically acceptable active agent would have been obvious over the active ingredients include analgesics (acetylsalicylic acid), antibiotics (amoxicillin), antidepressants (fluoxetine) and antihypertensives (verapamil), as taught by Breitenbach (Col. 1, line 38 to Col. 2, line 38). The limitation of the non-thermosetting polymerized plastics material that contains at least one polyol and at least one non-thermosetting modifier would have been obvious over the polyols mannitol, sorbitol and xylitol and the starches, as taught by Breitenbach (Col. 3, lines 21-22 and Col. 3, lines 33-35). The limitation of the non-thermosetting polymer would have been obvious over the cellulose derivatives such as methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose taught by Jane (Col. 4, lines 58-62). The injection molding would have been obvious over the injection molding taught by Jane (Col. 6, lines 24-30).

Regarding instant claims 4, 23-24, the limitation of the non-thermosetting polymerized plastics material that contains at least one polyol and at least one non-thermosetting modifier would have been obvious over the polyols mannitol, sorbitol and xylitol and the starches, as taught by Breitenbach (Col. 3, lines 21-22 and Col. 3, lines 33-35).

Regarding instant claims 7 and 25, the limitation of the starch would have been obvious over the starches taught by Breitenbach (Col. 3, lines 21-22) and over the corn starch, wheat starch, rice starch and potato starch taught by Jane (Col. 4, lines 36-44).

Regarding instant claim 27, the limitation of the non-thermosetting polymer that is present in an amount of 2 to 90% w/w would have been obvious over the 5 to 20 parts of filler such as starch, cellulose derivatives such as methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose taught by Jane (Col. 4, lines 25-62).

Regarding instant claims 11 and 29, the limitation of the disintegrant would have been obvious over the sodium carboxymethylcellulose taught by Jane (Col. 4, lines 58-62) and the guar gum, locust bean gum, and agar as taught by Jane (Col. 4, lines 54-57).

Regarding instant claims 12 and 30, the lubricant would have been obvious over the talc, as taught by Breitenbach (Col. 3, line 53).

Regarding instant claims 13 and 31, the opacifier would have been obvious over the calcium carbonate used as a bleaching/whitening agent, as taught by Jane (Col. 5, lines 5-7).

Regarding instant claims 14 and 32, the pharmaceutically acceptable active agent would have been obvious over the active ingredients include analgesics (acetylsalicylic acid), antibiotics (amoxicillin), antidepressants (fluoxetine) and antihypertensives (verapamil), as taught by Breitenbach (Col. 1, line 38 to Col. 2, line 38).

Regarding instant claims 20 and 37, the limitation of the microcellular polymeric material that results in a closed cell foam would have been obvious over the closed cell structure as taught by Jane (Col. 8, lines 12-14).

Regarding instant claim 21, the limitation of a rigid microcellular foam would have been obvious over the solid, foamed active ingredient preparation as taught by Breitenbach (Col. 1, lines 5-7 and Col. 5, lines 2-5) and by the closed cell structure as taught by Jane (Col. 8, lines 12-14). The limitation of a solid excipient having voids with a maximum void dimension in the range from about 2 to 100 microns would have been obvious over the closed cell structure with an average cell diameter of about 50μm, as taught by Jane (Col. 8, lines 12-14). The limitation of a void fraction in the range of about 5 to 95 percent would have been obvious over the solid foamed active ingredient preparations taught by Breitenbach (Col. 1, lines 5-7) because Breitenbach teaches that "the degree of foaming of the active ingredient preparation can be controlled by the amount of blowing agent added and the extrusion temperature. A high degree of foaming results in a lower density and thus a high rate of dissolution of the active ingredient form" (Col. 4, lines 61-65). One with ordinary skill in the art would modify the process parameters by varying the amount of blowing agent and the extrusion temperature and achieve the desired void fraction. The recited void fraction range would

have been an obvious variant unless there is evidence of criticality or unexpected results. The limitation of the solid excipient comprising a thermosetting polymerized plastic material and an active pharmaceutical agent combined in a homogenous solid mixture would have been obvious over the solid foamed active ingredient preparations taught by Breitenbach (Col. 1, lines 5-7). The limitation of optionally comprising a sweetener, a disintegrant, a binder, a lubricant or an opacifier would have been obvious over the lubricants (stearates of aluminum or calcium) taught by Breitenbach (Col. 3, lines 26-60) and the additives such as lubricants and colorants as taught by Jane (Col. 5, lines 11-35).

Regarding instant claim 38, the limitation of the homogenous solid mixture that has a sufficiently high solubility in saliva would have been obvious over the “solid, foamed active ingredient preparations ... which comprise the active ingredient homogenously dispersed in the polymeric matrix, dissolve very rapidly and thus permit rapid release of the active ingredient”, as taught by Breitenbach (Col. 6, lines 18-22).

Regarding instant claim 39, the voids that are in the form of closed cells would have been obvious over the closed cell structure taught by Jane (Col. 8, lines 12-14).

Regarding instant claim 40, the limitation of the rigid microcellular foam that is enclosed within a skin would have been obvious over the “closed active ingredient forms, i.e., forms in which the layer comprising active ingredient is completely enveloped by a layer without active ingredient” as taught by Breitenbach (Col. 5, lines 9-60). Breitenbach teaches the "production of multilayer partially or completely foamed forms comprising active ingredients by coextrusion. This entails at least two compositions ... at least one of which comprises an active ingredient and at least one of

which is impregnated …" (Col. 5, lines 9-15). One with ordinary skill in the art would find it obvious to completely impregnate the active ingredient layer with another active ingredient layer during the process of routine experimentation.

Regarding instant claim 41, the limitation of the overall density of the dosage form that is substantially less than that of stomach fluids, whereby the dosage form is gastro-retentive would have been obvious because Breitenbach teaches that "the degree of foaming of the active ingredient preparation can be controlled by the amount of blowing agent added and the extrusion temperature. A high degree of foaming results in a lower density and thus a high rate of dissolution of the active ingredient form" (Col. 4, lines 61-65). One with ordinary skill in the art would modify the density of the dosage form with respect to the density of stomach fluids during the process of routine experimentation in order to make the dosage form gastro-retentive.

Regarding instant claim 51, the limitation of the non-thermosetting modifier that is present in an amount of 5 to 50% w/w would have been obvious over the 5 to 20 parts of filler such as starch taught by Jane (Col. 4, lines 25-44).

Regarding instant claims 52-54 and 57-58, the limitation of the polyol that is present in an amount of 5 to 70% w/w, in an amount of 5 to 50% w/w, and in an amount of 5 to 25% w/w would have been obvious over the 5 to 60 parts of plasticizer such as mannitol, and maltitol taught by Jane (Col. 3, lines 44-64).

Regarding instant claims 55-56, the limitation of the non-thermosetting modifier that is present in an amount of 2 to 90% w/w, and in an amount of 5 to 50% w/w would have been obvious over the 5 to 20 parts of filler such as starch taught by Jane (Col. 4,

lines 25-44). The recited range of the non-thermosetting modifier would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 59, the limitations of the formulations are obvious over the polyols (mannitol, sorbitol and xylitol) taught by Breitenbach (Col. 3, lines 21-22 and Col. 3, lines 33-35) in view of the 5 to 20 parts of filler such as starch taught by Jane (Col. 4, lines 25-44), the 5 to 60 parts of plasticizer such as mannitol, and maltitol taught by Jane (Col. 3, lines 44-64) and the hydroxypropylcellulose taught by Jane (Col. 4, lines 58-62).

12. Claims 8 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US 6,150,424) in view of Jane et al. (US 5,710,190) and De Bock et al. (US 5,428,150).

The teachings of Breitenbach and Jane are stated above.

Breitenbach and Jane do not expressly teach a maltodextrin as a non-thermosetting modifier.

De Bock teaches “a process for the extrusion of a starch-containing composition to produce a material suitable for the production of moulded articles in which the composition contains in addition to the starch a starch degradation product selected from starch hydrolysis products having DE's of 1 to 40, particularly a maltodextrin …” (Abstract). “The hydrolysis products used in the process … are preferably maltodextrins and more preferably have DE values of 2 to 20” (Col. 3, lines 50-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a solid, foamed active ingredient preparation, as taught by

Breitenbach, combine it with the foamed microcellular composition, as taught by Jane, further combine it with the maltodextrins, as taught by De Bock, and produce the instant invention.

One of ordinary skill in the art would do this because De Bock teaches that maltodextrins are degradation products of starch and the lower the DE value of the maltodextrin the less the extent of starch degradation (Col. 3, lines 36-47). One with ordinary skill in the art would find it obvious to try maltodextrin in the solid, foamed active ingredient preparation and the starches taught by Breitenbach (Col. 3, lines 21-22) and in the foamed microcellular composition with the corn starch, wheat starch, rice starch and potato starch taught by Jane (Col. 4, lines 36-44) with a reasonable expectation of success of producing a functional molded microcellular polymeric dosage form.

Regarding instant claims 8 and 26, the limitation of the non-thermosetting modifier that is a maltodextrin would have been obvious over the maltodextrins and starches taught by De Bock (Abstract and Col. 3, lines 50-52) and over the starches taught by Breitenbach (Col. 3, lines 21-22) and Jane (Col. 4, lines 36-44).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615